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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,908	08/27/2003	Scott J. Brabec	P-9676.00	4394

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EXAMINER
ALTER, ALYSSA M

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

C

Office Action Summary	Application No.	Applicant(s)	
	10/648,908	BRABEC ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/19/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

1. Claim 5 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claiming of structures being in contact with or implanted within the body amounts to an inferential recitation of the body, which renders these claims non-statutory. The examiner recommends changing "pierces tissue" in claim 5 to --adapted to pierce tissue--.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 6 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The examiner is unsure how the Applicant quantifies the smoothness of the surface of the electrode. The examiner is unsure how the microscopic surface could be greater than the macroscopic surface.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

1. Claims 1-8, 11-13, 15-16, 23-26 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Mulier et al. (US 5,431,649). Mulier et al. discloses a method and apparatus for R-F ablation with "an ablation catheter employing a helical electrode intended to be screwed into the myocardium at the site intended for ablation"(col. 1, lines 65-67). "The helical electrode is hollow, and the conductive solution is applied through one or more apertures in the electrode"(col. 2, lines 13-15).

The functional language and introductory statement of intended use of claims 1 and 23 has been carefully considered but are not considered to impart any further structural limitations over the prior art. Also, Mulier et al. discloses in col. 2, lines 15-25, the dispersion of Ringer solution, which has a higher conductivity than blood or cardiac muscle, to lower the electrical resistance. Therefore, the first current density generated within the lead is smaller than the second current density generated in the Ringer's solution and cardiac muscle or blood combination.

As to claims 1 and 23, figure 2 discloses a catheter with two conduction coils 32 and 34, tubing 30 for the delivery of Ringer's solution, the insulate housing 12 and the helical electrode 14. The examiner considers the cavity to be the lumen of the insulate housing 12, in which the conductor (coil 32), conductive structure (coil 34) and the electrode surface (tubing 30) are disposed. "The stainless steel tubing serves as an additional conductor, coupling electrode 14 to electrical connector 24 and enhancing the overall conductivity of the catheter"(col. 4, lines 41-44). Also, the "coils 32 and 34 also

serve as conductors. As illustrated, tubing 30 is between metal coils 32 and 34 and helical electrode 14"(col. 4, lines 62-64).

Further, as to claims 1, 7 and 12, the conductive solution, considered to be the conductive medium, fills the tubing 30 and is dispersed through ports 38,40 and 42 on the helical electrode 14 as seen in figure 3. Also, "electrode 44, illustrated in FIG. 4 is a second alternative embodiment of a helical electrode corresponding to electrode 14, but with the addition of an insulative sleeve 46, which covers the proximal portion of the electrode. Sleeve 46 limits the application of R-F energy to the distal portion of the electrode. Optionally, additional exit ports corresponding to ports 38, 40 and 42 illustrated in FIG. 43 may also be employed in conjunction with electrode 44. These additional exit ports may be limited to the exposed, uninsulated portion of electrode 44, or may extend along the entire length of electrode 44"(col. 5, lines 17-28). Therefore, since part of the helical electrode can be insulated, the examiner considers the insulated portion to be the insulated helical fixation and the uninsulated portion to be the second electrode.

As to claims 2-4, 8, 11, 13 and 24-25, the examiner considers section 28 to be a stud. The examiner also considers the port to be the opening in section 28, or stud, where the helix electrode extends from the lead body. Since the helix extends from the opening in the lead, it is fitted within the port and is thus flush with the port and circumscribed by the port.

As to claims 5, the ablation catheter employs "a helical electrode intended to be screwed into the myocardium at the site intended for ablation"(col. 1, lines 65-67).

As to claims 15 and 30, since Mulier et al. utilizes Ringer's solution as the conductive solution, or conductive medium, and The American Heritage Stedman's Medical Dictionary defines Ringer's solution as a "salt solution" {see Reference U} which is a saline solution. Therefore, Mulier et al. discloses the use of a saline solution.

As to claims 16, Mulier et al. discloses the requirement of "a second element (e.g. a guide catheter or guide wire) for advancing and positioning the catheter at its desired location, it is anticipated that the basic apparatus disclosed above may also be incorporated into catheters which themselves are steerable or deflectable, similar to R-F ablation catheters presently in clinical investigation"(col. 6, lines 6-13). Therefore, the lead with the helical fixation member would have to be capable of being withdrawn from the guide catheter, thus making the helical fixation member retractable.

2. Claims 1-8, 11-13, 16-18, 20-21, 23-26, 31-32 and 34-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Peterfeso et al. (US 6,298,272). Peterfeso et al. discloses an implantable lead which "comprises a lead body 11, an elongate conductor 13 contained within the lead body, and a lead tip 20 with an optional retractable tip assembly 24 contained in the lead tip 20. In addition, a stylet 14 is shown inserted into the lead body 11. A helix 100 (FIGS. 2A-5A), which consists of an electrical conductor coil, is contained in the retractable lead tip 24"(col. 8, lines 24-30).

Also, "depending on the embodiment, the fixation helix/piston assembly may be electrically active or inactive. The electrode collar, housing, and base all house the fixation helix/piston assembly. The proximal end of the electrode collar is attached to the distal end of the housing. Furthermore, the proximal end of the housing is attached

to the distal end of the base, and the proximal end of the base is directly attached to the conductor coils of the lead. A mesh screen may be attached to the distal tip of the electrode collar. The mesh screen, in another embodiment, is electrically active and serves as the electrode on the distal tip assembly. The tip (e.g., a helix) may then be fully insulated to increase the impedance of the tip or may be partially insulated (with preselected areas of the helix being insulated and other areas being non-insulated) to adjust the impedance of the tip to the specific or optimal levels desired"(col. 4, lines 44-59).

The functional language and introductory statement of intended use of claims 1 and 23 has been carefully considered but are not considered to impart any further structural limitations over the prior art. Since Peterfeso et al. utilizes a high impedence electrode with a conductor in contact with an electrode surface and a secondary electrode surface for delivering current out from the port as claimed by the Applicant, Peterfeso et al. is therefore capable of being used two deliver two current densities for each electrode surface. In addition nothing prevents Peterfeso et al. from generating two current densities on the two electrode surfaces, the first of which being smaller than the second current density. Therefore, the electrode surfaces are capable of generating differing current densities.

As to claims 1 and 23, the examiner considers the conductive structure to be the housing 380 which contacts the conductor through the base 360 and the electrode surface, which the examiner considers the electrode collar 40 *and mesh screen 330*, as seen in figure 2A. The base and piston assembly, which fills the lumen or cavity of the

lead, are considered by the examiner to be the conductive medium in intimate contact with the electrode surface, via the conductive housing and the helix fixation member. The helix has two portions, as seen in figure 6, one of which is the insulated portion 804, thus creating a insulated helical fixation member and the other portion being electrically conductive or uninsulated 806, thus being a second electrode.

As to claims 2-5, 7, 11 and 24-25, since the second electrode surface is in a helical formation, it circumscribes the port and is flush with the port until it is extended to protrude through the mesh groove 370 as in figure 2B. "A stylet knob 154 is coupled with the stylet 14 for rotating the stylet 14 and advancing the helix 100 into tissue of the heart"(col. 9, lines 2-4).

As to claims 8 and 13, the piston has a stylet slot 354 as seen in figure 2A. The examiner considers the stylet and reciprocal slot to be a stud that joins the conductor to the helical fixation member.

As to claims 12 and 16, as stated above, the helix has two portions, as seen in figure 6, one of which is the insulated portion 804, thus creating a insulated helical fixation member and the other portion being electrically conductive or uninsulated 806, thus being a second electrode. Also, the fixation lead is retractable.

As to claims 21 and 35, the examiner considers the steroid-loaded monolithic controlled release device (MCRD) to be the rods 81 for dispersing steroid material as seen in figure 4A.

As to claims 17-18, 20, 31-32 and 34, "the helix 100 is formed of electrically conductive material offering low electrical resistance and also resistant to corrosion by

body fluids. A biocompatible metal, such as titanium or platinum-iridium alloy is an example of a suitable material"(col. 8, lines 41-45). The examiner considers the platinum-iridium alloy to comprise both iridium-oxide and platinum particles.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 10, 14, 17-20, 22, 28-29 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier et al. (US 5,431,649). Mulier et al. discloses the claimed invention but does not disclose expressly the electrode surface composition. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the electrode surface as taught by Mulier et al., with the platinum black particles, iridium-oxiode, ruthenium-oxide, titanium-nitride, because Applicant has not disclosed the specific compositions provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the electrode surface as taught by Mulier et al., because both electrodes are compatible with the human body and therefore, capable of being used within an implantable medical device, such as a lead.

Therefore, it would have been an obvious matter of design choice to modify electrode surface composition to obtain the invention as specified in the claim(s).

Also, as to claims 14 and 29, Mulier et al. discloses the claimed invention but does not disclose expressly the conductive medium being a hydrogel. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify saline solution as taught by Mulier et al., with the hydrogel, because Applicant has not disclosed the specific compositions provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the saline solution as taught by Mulier et al., because both mediums are in electrical contact with the electrodes, are disposed within the lead cavity and are capable of conducting electrical current.

Therefore, it would have been an obvious matter of design choice to modify conductive medium to obtain the invention as specified in the claim(s).

In addition, as to claims 10 and 28, Mulier et al. discloses the claimed invention but does not disclose expressly the conduction structure of the first electrode being greater or equal 10 mm^2. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the conduction structure of the first electrode as taught by Mulier et al., with the range of greater or equal 10 mm^2, because Applicant has not disclosed the range provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the conductive structure of the first

electrode as taught by Mulier et al., because both first electrode surfaces are contained within the lead cavity and conduct electrically energy to the body.

Therefore, it would have been an obvious matter of design choice to modify conductive medium to obtain the invention as specified in the claim(s).

2. Claims 10, 14-15, 17-20, 22 and 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterfeso et al. (US 6,298,272). Peterfeso et al. discloses the claimed invention but does not disclose expressly the electrode surface composition. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the electrode surface as taught by Peterfeso et al., with the platinum black particles, iridium-oxiode, ruthenium-oxide, titanium-nitride, because Applicant has not disclosed the specific compositions provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the electrode surface as taught by Peterfeso et al., because both electrodes are compatible with the human body and therefore, capable of being used within an implantable medical device, such as a lead.

Therefore, it would have been an obvious matter of design choice to modify electrode surface composition to obtain the invention as specified in the claim(s).

Also, as to claims 14-15 and 29-30, Peterfeso et al. discloses the claimed invention but does not disclose expressly the conductive medium being a hydrogel or saline solution. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify conductive medium as taught by Peterfeso et al., with

the hydrogel or saline solution, because Applicant has not disclosed the specific compositions provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the conductive medium as taught by Peterfeso et al., because mediums are in electrical contact with the electrodes and are disposed withing the lead cavity.

Therefore, it would have been an obvious matter of design choice to modify conductive medium to obtain the invention as specified in the claim(s).

In addition, as to claims 10 and 28, Peterfeso et al. discloses the claimed invention but does not disclose expressly the conduction structure of the first electrode being greater or equal 10 mm^2. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the conduction structure of the first electrode as taught by Peterfeso et al., with the range of greater or equal 10 mm^2, because Applicant has not disclosed the range provides an advantage, is used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the conductive structure of the first electrode as taught by Peterfeso et al., because both first electrode surfaces are contained within the lead cavity and conduct electrically energy to the body.

Therefore, it would have been an obvious matter of design choice to modify conductive medium to obtain the invention as specified in the claim(s).

3. Claims 9, 17-18, 20, 22, 27, 31-32 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peterfeso et al. (US 6,298,272) or Mulier et al. (US 5,431,649)

in view of Gates (US 5,408,744). Peterfeso et al. and Mulier et al. discloses the claimed invention except for the electrode surface composition. Gates teaches that it is known to utilize platinum black, titanium, tantalum, iridium oxides and nitrides as set forth in column 7, lines 50-63. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrode surface as taught by Peterfeso et al. and Mulier et al. with the electrode surface composition as taught by Gates, since it was known in the art that the compositions are all electrically conductive materials used for electrode surfaces and can therefore be altered to meet specific patient needs.

As to claims 10 and 28, Peterfeso et al. and Mulier et al. disclose the claimed invention except for the electrode range. Gates teaches that it is known to utilize electrodes within the range of $0.1mm^2$ to $4.0mm^2$ as set forth in column 4, lines 57-63. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrodes as taught by Peterfeso et al. and Mulier et al. with the electrode range as taught by Gates, in order to increase the impedance without increasing thresholds or negatively impacting sensing capabilities.

4. Claims 21 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mulier et al. (US 5,431,649) in view of Altman et al. (US 6,086,582). Mulier et al. discloses the claimed invention except for the steroid-loaded monolithic controlled release device (MCRD). Altman et al. teaches that it is known to dispense steroid-based drugs slowly through a lead, as disclosed in col. 3, lines 33-37. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

have modified the dispensed fluid as taught by Mulier et al. with the drug delivery means as taught by Altman et al, in order to modify the treatment based on specific patients need and to facilitate localized drug delivery.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

1. Ley et al. (US 6,360,129) discloses mannitol/hydrogel cap for tissue-insertable connections.

2. Stokes et al. (US 5,282,844) discloses high impedance, low polarization, low threshold miniature steroid eluting pacing lead electrodes.

3. Lucchesi et al. (US 6,129,751) discloses cardiac lead with active fixation and biocompatible lubricant.

4. Berthelsen (US 4,953,564) discloses a screw-in drug eluting lead.

5. Moaddeb (US 5,324,325) discloses a myocardial steroid releasing lead.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George Manuel

Alyssa M Alter
Examiner
Art Unit 3762

AMA